Docket No.: 27779/36104

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joseph S. Podolski			I hereby certify that this paper and the documents referred to as enclosed
Serial No.: 09/494,627			herewith are being deposited with the
		)	United States Postal Service as First
Filed: January 31, 2000			Class Mail, postage prepaid, in an
		)	envelope addressed to:
For:	METHODS FOR TREATMENT OF	· )	Assistant Commissioner for Patents,
	MALE ERECTILE DYSFUNCTION	) .	Washington, D.C. 20231, on this date:
		)	
Group	Art Unit: 1614	)	May 1, 2000
Evami	iner: To be assigned	)	Rand. Cawl M
·	mor. To be abbigined	í	Thomas A. Cawley, Jr., Ph.D.
	·	Ś	Registration No. 40,944
	· ·	)	Attorney for Applicant
		)	

## INFORMATION DISCLOSURE STATEMENT WITH FORM PTO-1449

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

In compliance with 37 C.F.R. §1.97 and the continuing duty of disclosure under 37 C.F.R. §1.56, the applicant calls to the attention of the examiner the enclosed documents, as listed on the attached Form PTO-1449, which may be considered material to the examination of the above-identified patent application.

All listed documents were previously of record in the parent application (serial no. 09/154,677, filed September 17, 1998, pursuant to 37 C.F.R. §1.98(d), copies of the documents are not submitted herewith.

This statement and the accompanying items of information, including a Form PTO-1449, are being submitted before receipt of a first official action in the above-identified patent application. Accordingly, it is submitted that no fee is due in this matter under 37 C.F.R. §1.97(b). However, if it is determined that any appropriate fee is due, the Commissioner is hereby authorized to charge deposit account no. 13-2855.

Respectfully submitted,

MARSHALL, O'TOOLE, GERSTEIN, MURRAY & BORUN 6300 Sears Tower 233 South Wacker Drive

Chicago, Illinois 60606-6402 (312) 474-6300

By:

Thomas A. Cawley, Jr., Ph.D.

Reg. No: 40,944

May 1, 2000

Atty. Docket No. Serial No. . U.S. Department of Commerce Form PTO-1449 (Modified) Patent and Trademark Office 27779/36104 09/494,627 Applicant Podolski, J. INFORMATION DISCLOSURE STATEMENT Group Filing Date January 31, 2000 1614

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS							
*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	A1	3,943,246	03/09/76	Sturmer, E.	424	177	
	A2	4,127,118	11/28/78	Latorre, A.	128	79	
	A3	4,139,617	02/13/79	Grunwell, J.F. et al.	424	238	
	A4	4,530,920	07/23/85	Nestor, J.J. et al.	514	15	
	A5	4,801,587	01/31/89	Voss, G. et al.	514	248	
	A6	4,863,911	09/05/89	Anderson, W.R. Jr. et al.	514	176	
	A7	4,885,173	12/05/89	Stanley, T.H. et al.	424	440	
	A8	5,059,603	10/22/91	Rubin, D.	514	264	
	A4	5,065,744	11/19/91	Zusmanovsky, Z.A.	128	79	
	A10	5,079,018	01/07/92	Ecanow, B.	426	385	
	A11	5,145,852	09/08/92	Virag, R.	514	253	
	A12	5,236,904	08/17/93	Gerstenberg, T. et al.	514	12	
	A13	5,256,652	10/26/93	El-Rashidy, R.	514	58	
	A14	5,270,323	12/14/93	Milne, G.M. Jr. et al.	514	309	
	A15	5,298,261	03/29/94	Pebley, W.S. et al.	424	488	
	A16	5,399,581	03/21/95	Laragh, J.H. et al.	514	396	
	A17	5,565,466	10/15/96	Gioco, D.M. et al.	514	280	
	A18	5,731,339	03/24/98	Lowrey, F.	514	400	

**EXAMINER** 

DATE CONSIDERED

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 27779/36104	Serial No. 09/494,627	
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. (Use several sheets if necess		Filing Date January 31, 2000	Group 1614	

FOREIGN PATENT DOCUMENTS								
							Translation	
*Examiner Initials		Document Number	Publication Date	Country	Class	Subclass	Yes	No
	В1	0 357 581	3/7/90	EP				
	B2	WO 95/05172	02/23/95	WIPO				

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
C1	AC-Di-Sol®, Croscarmellose Sodium, NF and Ph.Eur. The Premier Super Disintegrant For Wet and Dry Granulation Tablets And Capsules (Accelerates DisSolution) (Product Description Brochure); FMC Corporation, Philadelphia, PA, pp. 1-9 (1988).
C2	Althof, S.E. et al., "Sexual, Psychological, and Marital Impact of Self-Injection of Papaverine and Phentolamine: A Long-Term Prospective Study," <i>Journal Sex and Marital Therapy</i> , 17(2):101-112 (1991).
C3	Azadzoi, K.M. et al., "Effects of Intracavernosal Trazadone Hydrochloride: Animal and Human Studies," J. Urology, 144(5):1277-1282 (November, 1990).
C4	Barnett, A.J. et al., "The Action Of "Regitine" In Man With Special Reference To Its Adrenergic Blocking Action," Australasian Anals of Medicine, 1:109-119 (1952).
C5	Beavo, J.A. et al., In: Advances in Second Messenger and Phosphoprotein Research, Greengard et al., (eds.), Volume 22, pgs. 1-38 (1988).
C6	Biotechnology Newswatch, "Nice try, but no Viagra, say experts reviewing new potency pills," pp. 4-5 (June, 1998).
C7	Brindley, G.S., "Pilot experiments on the actions of drugs injected into the human corpus cavernosum penis," <i>Br. J. Pharmac.</i> , 87:495-500 (1986).
C8	Brindley, G.S., "Cavernosal Alpha-Blockade: A New Technique for Investigating and Treating Erectile Impotence," <i>Brit. J. Psychiat.</i> , 143:332-337 (1983).

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INFORMATION DISCLOS		Filing Date January 31, 2000	Group 1614	

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
	C9	Brindley, G.S., "Cavernosal alpha-blockade and human penile erection," <i>J. Physiol.</i> , 342:24P (1983).
	C10	Corriere, J.N. Jr. et al., "Development of Fibrotic Penile Lesions Secondary to the Intracorporeal Injection of Vasoactive Agents," J. Urology, 140:615-617 (September, 1988).
	C11	Dawson, A. et al., "The Transient Anti-Hypertensive Effect of Phentolamine in Patients Receiving Beta-Blocker Treatment," J. Int. Med. Res., 5:462-464 (1977).
-	C12	Diedrichs, W. et al., "Reduction of Sympathetic Influence on Penile Erection by Phentolamine," Urol. Int., 46:64-66 (1991).
	C13	Georgopoulos, A.J. et al., "Treatment of Chronic Heart Failure with Slow Release Phentolamine," Europ. J. Clin. Pharmacol., 13:325-329 (1978).
	C14	Gissinger, D. et al., "A Comparative Evaluation of the Properties of some Tablet Disintegrant," Drug Development and Industrial Pharmacy, 6(5):511-536 (1980).
	C15	Godbillion et al., "Determination of the Major Metabolite of Phentolamine in Human Plasma And Urine By High-Performance Liquid Chromatography," J. Chromatography, 222:461-466 (1981)
	C16	Gould, L.A. et al., "Oral Therapy with Phetolamine in Chronic Congestive Heart Failure," Chest, 75(4):487-491 (April, 1979).
	C17	Gwinup, G., "Oral Phentolamine in Nonspecific Erectile Insufficiency," <i>Annals Internal Medicine</i> , pgs. 162-163 (July, 1988).
	C18	Imhof, P.R. et al., "Human Pharmacology of Orally Administered Phentolamine," In: Phentolamine in Heart Failure and Other Cardiac Disorders, Taylor, S.H., and Gould, L.A., (eds.), Ben Huber, pp. 11-22 (1976).
	C19	Larsen, E.H. et al., "Fibrosis of Corpus Cavernosum After Intracavernous Injection of Phentolamine/Papaverine," <i>Journal Urology</i> , 137:292-293 (February, 1987).
	C20	Marriot, H.J.L., "An Alarming Pressor Reaction To Regitine," 46(5):1001-1002 (May, 1957).

	EXAMINER	DATE CONSIDERED
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		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
	C21	McDonnell, S.M. et al., "Imipramine-induced Erection, Masturbation, and Ejaculation in Male Horses," <i>Pharmacol. Biochem. Behav. (USA), 27(1)</i> :187-191 (May, 1987) (ABSTRACT).
	C22	Montorsi, F. et al., "Clinical Reliability of Multi-Drug Intracavernous Vasoactive Pharmacotherapy for Diabetic Impotence," Acta Diabetol., 31:1-5 (1994).
	C28	NIH Consensus Conference, "Impotence," NIH Consensus Development Panel on Impotence, Journal American Medical Association, 270(1):83-90 (1993).
	C24	Pfister et al., "Estimation of the Plasma Concentration and Course of Action of Phentol-amine Based On Its Inhibitory Effect On Adrenaline-Induced Platelet Aggregation," Br. J. Clin. Pharmac., 5:175-180 (1978).
	C25	PHYSICIANS' DESK REFERENCE, 37 Edition, pg. 409 and 864 (1983).
	C26	Ruskin, J.N. et al., "Primary Pulmonary Hypertension Treated With Oral Phentolamine," Annals of Internal Medicine, 90:772-774 (1979).
	C27	Schreiber, R. et al., "Hemodynamic Improvement following a Single Dose of Oral Phentolamine: Administration in Patients with Chronic Low Output Cardiac Failure," Chest, 76(5):571-575 (November, 1979).
-	C28	Selvaag, O. et al., "Experiences with Regitin (A New Vasodilator Compound),"  Acta Medica Scandinavica, Vol. CXLVI, fase. III, pp. 209-215 (1953).
	C29	Sioufi, A. et al., "Gas Chromatographic Determination of Phenentolamine (Regitine) in Human Plasma and Urine," <i>Journal of Chromatography</i> , 222:429-435 (1981).
	C30	Sonda, L.P. et al., "The Role of Yohimbine for the Treatment of Erectile Impotence," J. Sex & Marital Ther., 16(1):15-21 (1990).
	C31	Terrett, N.K. et al., "Sildenafil (VIAGRA <sup>TM</sup> ), A Potent and Selective Inhibitor of Type 5 cGMP Phosphodiesterase with Utility for the Treatment of Male Erectile Dysfunction," Bioorganic & Medicinal Chemistry Letters, 6(15):1819-1824 (1996).
	C32	The Extra Pharmacopoeia: The authoritative reference work on drugs and medicines in current use, Twenty-sixth Edition, 2 pages (1988).

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	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
C33	Trapold, J.H. et al., "Pharmacological and Toxicological Studies on 2-(N-p'tolyl-N-(m'-Hydroxypheyl)-Aminomethyl)-Imidazoline (C-7337), a New Adrenergic Blocking Agent" pp. 119-127 (1950).
C39	United States Pharmacopeia, Twentieth Revision, Official from July 1, 1980, The National Formulary, Fifteenth Edition, Official from July 1, 1980, United States Pharmacopeial Convention, Inc., Rockville, Maryland, pp. 615-617 (1979).
C35	Virag, R. et al., "Intracavernous Injection of Papaverine as a Diagnostic and Therapeutic Method in Erectile Failure," Angiology, 35:79-87 (1984).
C36	Virag, R., "Intracavernous Injection of Papaverine for Erectile Failure," Lancet, ii:938 (October, 1982).
C37	Wagner, G. et al., "Buccal Phentolamine-A pilot trial for male erectile dysfunction at three separate clinics," Int. J. Impotence Res., 6(Suppl. 1):D78 (1994).
C38	Williams, Textbook of Endocrinology, p. 313 (Circa, 1976).
C39	Zorgniotti, A.W.,""On Demand" Oral Drug For Erection In Impotent Men," J. Urology (AUA Eighty-Seventh Annual Meeting May 10-14, 1992), 147(4)(Suppl.):308A (April, 1992) (ABSTRACT 382).
C40	Zorgniotti, A.W., "Experience with Buccal Phentolamine Mesylate for Impotence," International Journal of Impotence Research, 6(1):37-41 (March, 1994).
C41	Zorgniotti, A.W. et al., "Auto-injection of the Corpus Cavernosum with a Vasoactive Drug Combination for Vasculogenic Impotence," Journal Urology, 133:39-41 (1985).

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